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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,909	12/16/2005	Robert Frigg	10139/02002	3108
76960 7590 11/18/2008 Fay Kaplun & Marcin, LLP 150 Broadway, suite 702 New York, NY 10038				
			EXAMINER WOODALL, NICHOLAS W	
			ART UNIT 3775	PAPER NUMBER
			MAIL DATE 11/18/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,909

Applicant(s)

FRIGG ET AL.

Examiner

Nicholas Woodall

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment received on 08/14/2008.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 19-25, 27, 31, 34-38, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813).

Durham discloses a device comprising an intramedullary pin (20), a bone fixation element (60), a sliding sleeve (40), and a locking mechanism (90). The intramedullary rod includes a first longitudinal axis, a proximal portion, a distal portion, and at least one transverse opening through the proximal portion of the pin. The transverse opening forms an oblique angle with the first longitudinal axis of the pin. The bone fixation element includes a second longitudinal axis, a first end, a second end, and a shaft. The sliding sleeve includes a central bore, an interior profile, and an exterior profile surface. The bone fixation device, sliding sleeve, and the locking mechanism are capable of being inserted through the transverse opening while assembled. The bone fixation element further includes a threaded longitudinal bore at the second end of the element. The locking mechanism is a fixing screw having a screw head has a diameter larger than the diameter of the threaded shank. The outside thread of the fixing screw

corresponds to the threaded bore of the bone fixation element. The bone fixation element is axially fixed relative to the sliding sleeve. The rear end of the sliding sleeve extends past the second end of the bone fixation device at least 0.01 mm. The first end of the bone fixation element includes a screw thread. The locking mechanism is capable of limiting the axial displacement of the sliding sleeve relative to the intramedullary pin. The bone fixation element is a screw. Durham fails to disclose a device wherein the interior surface profile of the sliding sleeve is configured to permit free rotation of the bone fixation device relative to the sleeve and the transverse bore of the intramedullary pin having a non-circular cross-section (claims 19 and 37) and the exterior profile of the sliding sleeve having a cross-section complimentary to the cross-section of the transverse bore (claim 37). First, Durham does disclose that the interior surface profile of the sliding sleeve may include flat surfaces and the outer surface profile of the bone fixation device includes complementary flat surfaces, but Durham discloses that is a preferred embodiment and is not necessary for the invention to operate properly. Therefore, if the flat surfaces were to be omitted from the sliding sleeve and the bone fixation device, the interior surface profile of the sliding sleeve could have a circular cross-section and the outer surface profile of the bone fixation device could have a circular cross-section, which would permit the bone fixation element to rotate freely relative to the sliding sleeve. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to manufacture the interior surface profile of the sliding sleeve and the outer surface profile of the bone fixation of Durham with a circular cross-section, since applicant has not disclosed that such solve

any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing an interior surface profile of a sliding sleeve and the outer surface profile of a bone fixation element. In re Dailey and Eilers, 149 USPQ 47 (1966). Lawes teaches a device wherein the cross-section of a transverse bore is non-circular and complementary to the exterior profile of a sliding sleeve in order to prevent rotation of the sliding sleeve relative to an intramedullary pin and to allow the sleeve to slide axially within the transverse bore (column 3 lines 62-67). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Durham with a transverse bore having a noncircular cross-section that is complimentary to the exterior profile of the sliding sleeve in view of Lawes in order to prevent rotation of the sliding sleeve relative to an intramedullary pin and to allow the sleeve to slide axially within the transverse bore.

4. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Bramlet (U.S. Patent 6,648,889).

The combination of Durham as modified by Lawes disclose the invention as claimed except for the bone fixation element having a first annular groove and the internal surface of the sliding sleeve having a second annular groove, which are engaged by a ring element. Bramlet teaches a device that includes a nail element with a bore and a locking element with annular groove, which are engaged by a ring element in order to detent the axial movement of the locking element in the bore of the nail

element (column 8 lines 32-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the combination of Durham as modified by Lawes wherein the sleeve and bone fixation element of Durham as modified by Lawes with annular grooves and a ring element in view of Bramlet in order to detent axial movement of the bone fixation element in the sleeve.

5. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Fixel (U.S. Patent 4,432,358).

The combination of Durham as modified by Lawes discloses the invention as claimed except for the bone fixation element comprising an externally threaded portion at the second end (claim 28) and the locking mechanism including a nut with an internal thread (claim 29). Fixel teaches a device comprising a bone fixation element having external threads at a second end of the element and a locking mechanism including a nut having internal threads in order to engage the nut (column 3 lines 50-52) and to compress the broken portions of bone (column 2 lines 63-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the combination of Durham as modified by Lawes with a bone fixation element having external threads at the second end of the element and a locking mechanism which includes a nut with internal threads in view of Fixel in order to engage the nut and to compress the broken portions of bone.

6. Claims 30, 32, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Bresina (U.S. Patent 5,908,422).

The combination of Durham as modified by Lawes discloses the invention as claimed except for the bone fixation element including a plurality of helical blades. Bresina teaches a bone fixation element comprising a plurality of helical blades in order to minimize the tendency to cut through the cancellous bone tissue after implantation and provides the required stiffness to maintain a relative orientation of the bone fragments (column 2 lines 15-29). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Durham as modified by Lawes with a bone fixation element including a plurality of helical blades in view of Bresina in order to minimize the tendency to cut through the cancellous bone tissue after implantation and provides the required stiffness to maintain the relative orientation of the bone fragments.

7. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Durham (U.S. Patent 5,032,125) in view of Lawes (U.S. Patent 5,454,813) further in view of Bresina (U.S. Patent 5,908,422) further in view of Frigg (U.S. Patent 6,187,007).

The combination of Durham as modified by Lawes further modified by Bresina disclose the invention as claimed except for the helical blades having a pitch of at least 50 mm. Frigg teaches a bone fixation element wherein the helical blades have a pitch of at least 50 mm in order to not allow any torque to be transmitted to the femur head (column 2 lines 4-7). It would have been obvious to one having ordinary skill in the art at

the time the invention was made to provide the device of Durham as modified by Lawes further modified by Bresina with a bone fixation element comprising helical blades with a pitch of at least 50 mm in view of Frigg in order to not allow any torque to be transferred to the femur head.

Response to Arguments

8. The applicant's arguments filed 08/14/2008 have been fully considered but they are not persuasive. The applicant's argument that the screw (element 90) does is not capable of performing the function of locking rotation of the lag screw (element 60) is not persuasive. The applicant argues that surfaces 44 and 66 already prevent the rotation of the lag screw, but this argument is moot since the examiner has changed the surfaces as discussed in the rejections above. The screw is **fully capable of preventing at least a minimal amount of rotation of the lag screw if tightened, with or without surface 44 and 46** (emphasis added by the examiner). Therefore, element 90 is **fully capable of performing the functional limitations** of the claim. The applicant's argument that the flat surfaces (44 and 46) are not capable of being changed to circular surfaces is not persuasive (emphasis added by the examiner). As discussed in the previous actions Durham discloses a preferred embodiment that comprises flat surfaces to prevent rotation of the lag screw (column 2 lines 55-63 and column 3 lines 17-19). It is extremely clear by the disclosure that the embodiments shown in the figures and discussed in the disclosure are the preferred embodiments and do not encompass all the variations of the invention. As stated in column 2 lines 58-63, Durham discloses, "the sleeve **may include an engaging surface** formed on the

interior of the sleeve and adapted for cooperation with complementary engaging surface formed on the body member of the lag screw to prevent rotation of the lag screw within the sleeve" (emphasis added by the examiner). Durham simply states that the device may include engagement surfaces to perform the function if one so desired, which means that the device does not have to include the engagement surfaces and therefore may not be included in the device. The engagement surfaces are not disclosed as being critical to the function of the device and are capable of being modified without destroying the reference. Therefore, if the flat engagement surfaces were omitted the interior surface of the sleeve could have a circular cross-section permitting the screw to rotate freely within the sleeve. Durham simply states that the device may include engagement surfaces to perform the function if one so desired, which means that the device does not have to include the engagement surfaces and therefore may not be included in the device. Therefore, the surfaces may be modified in a way consistent with the knowledge of one of ordinary skill in the art without preserving the function because the structure and the function are not required to be included in the invention. The applicant's argument that assuming engaging surfaces (44 and 66) are not required by the disclosure of the reference is the use of improper hindsight is not persuasive. Any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA

1971). The examiner has not provided any new grounds of rejection making this office action **FINAL**.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is (571)272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas Woodall/

Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733